05-18-07

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CC

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of:	)	
	)	Before the Examiner
SAMARITANI, Fabrizio et al.	)	Hemant Khanna
	)	
Application No. 10/551,840	)	Group Art Unit
	)	1654
Filed January 20, 2006	)	
	)	
LIQUID PHARMACEUTICAL FORMATIONS OF FSH AND LH TOGETHER WITH A NON-IONIC SURFACTANT	)	Confirmation No 4228

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

1. List of All Patents, Publications, U.S. Applications, or Other Information

Pursuant to the provisions of 37 CFR 1.56, 1.97, and 1.98, Applicant requests consideration of the references listed on the attached PTO/SB/08 form(s) (commonly referred to as a PTO-1449 form) and/or the additional information identified below.

☒ I hereby certify that this correspondence is being deposited with the United States Postal Service as "**Express Mail** Post Office to Addressee" addressed to Commissioner for Patents, Mail Stop Amendment, P.O. Box 1450, Alexandria, VA 22313-1450, Mailing Label No. EM 079404242 US, on the date indicated below.

Sandy Elston
Typed/printed name of person signing this certificate

Signature

May 17, 2007
Date

05/21/2007 AADOF01 00000011 10551840

01 FC:1806 180.00 OP

2. Enclosed Legible Copies

2a. A legible copy of each foreign patent document and publication listed on the PTO/SB/08 form is enclosed,

☐ i. except, a copy is not provided for each reference previously cited by or submitted to the Patent Office in prior U.S. Patent Application Serial No. _____, filed _____ from which the present application claims priority under 35 U.S.C. §120.

☐ ii. except, a copy is not provided for each cumulative reference and enclosed reference identified below:

☐ 2b. A copy of the specification and drawings for each cited unpublished U.S. application.

☐ 2c. A copy of a Search Report or Written Opinion from a foreign patent office is also enclosed.

☐ 2d. Consideration of the enclosed additional and/or below discussed information is requested.

3. Concise Explanation of Relevance for Non-English Language Information

For each non-English language reference listed on the attached SB/08 form(s), reference is made to:

☐ 3a. an English language translation submitted herewith,

☐ 3b. foreign patent office Search Report (in the English language) submitted herewith,

☐ 3c. an English language translation of a foreign patent office Search Report submitted herewith,

☐ 3d. the concise explanation contained in the present application at page(s) ___,

☐ 3e. the concise explanation set forth in the attached English language abstract,

☒ 3f. a copy of a related patent publication (in the English language) cited herewith,

Foreign Patent Document	Corresponding English Language Patent Document
DE 41 17 078 A1	WO 92/21332

☐ 3g. the following concise explanation: ___.

4. Time for Filing

☐ 4a. This Information Disclosure Statement is submitted:

☐ i. for U.S. national applications or national stage PCT applications (not including CPAs and RCEs), within 3 months of filing or entry into national stage; or

☐ ii. for U.S. national applications, national stage PCT applications, CPAs or RCEs, before the first Office Action on the merits,

and thus no certification and/or fee is required.

☒ 4b. This information Disclosure Statement is submitted after three months from the filing date and after the first Office Action on the merits, but prior to the mailing date of a final Office Action or Notice of Allowance, and thus:

☐ i. the statement specified in 37 CFR §1.97(e) is provided below, or

☒ ii. a fee of $180.00 (set forth in 37 CFR §1.17(p)) is enclosed.

☐ 4c. This Information Disclosure Statement is submitted after the mailing date of a final Office Action or Notice of Allowance and prior to payment of the issue fee, and thus:

☐ i. the statement specified in 37 CFR §1.97(e) is provided below, and a fee of $ (set forth in 37 CFR §1.17(p)) is enclosed, or

☐ ii. a Request for Continued Examination (RCE) and fee of 37 CFR §1.17(e) has been filed.

☐ 4d. This Information Disclosure Statement is submitted after payment of the issue fee, and thus:

i. a Petition to Withdraw from Issue pursuant to 37 CFR §1.313(c)(2) has been filed, and

ii. a Request for Continued Examination (RCE) and fee of 37 CFR §1.17(e) has been filed.

5. Certification- Statement Under 37 CFR 1.97(e)

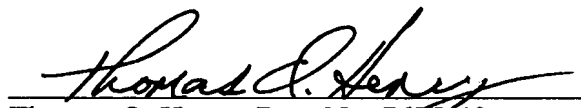
☐ 5a. It is hereby certified that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.

☐ 5b. A copy of a dated communication from a foreign patent office which clearly shows the statement is being submitted within three (3) months of the date on the communication is enclosed.

☐ 5c. It is hereby certified that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to my knowledge after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

The filing of this Information Disclosure Statement shall not be construed as an admission that the information cited is, or is considered to be, material to patentability as defined in §1.56(b). It is believed that no additional fees are required. Should any other fee be required, however, please charge such fee to Deposit Account No. 23-3030, but not to include any payment of issue fees.

Respectfully submitted,

By 

Thomas Q. Henry, Reg. No. 7675-49
Woodard, Emhardt, Moriarty, McNett & Henry LLP
111 Monument Circle, Suite 3700
Indianapolis, Indiana 46204-5137
(317) 634-3456

PTO/SB/17 (02-07)
Approved for use through 02/28/2007. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Effective on 12/08/2004.
Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

FEE TRANSMITTAL
For FY 2007

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT	($) $180.00

Complete if Known	
Application Number	10/551,840
Filing Date	January 20, 2006
First Named Inventor	Samaritani, Fabrizio et al.
Examiner Name	Hemant Khanna
Art Unit	1654
Attorney Docket No.	7541-6

METHOD OF PAYMENT *(check all that apply)*

☐ Check ☒ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): ____

☒ Deposit Account Deposit Account number: 23-3030 Deposit Account Name: Woodard, Emhardt, Moriarty, McNett & Henry LLP

For the above-identified deposit account, the Director is hereby authorized to: *(check all that apply)*

☐ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, **except for the filing fee**

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FEE CALCULATION

1. BASIC FILING, SEARCH, AND EXAMINATION FEES

	FILING FEES		SEARCH FEES		EXAMINATION FEES		
		Small Entity		Small Entity		Small Entity	
Application Type	Fee ($)	Fee ($)	Fee ($)	Fee ($)	Fee ($)	Fee ($)	Fees Paid ($)
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

2. EXCESS CLAIM FEES

Fee Description	Fee ($)	Small Entity Fee ($)
Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	200	100
Multiple dependent claims	360	180

Total Claims		Extra Claims	Fee ($)	Fee Paid ($)
	-20 or HP	=	x	=

HP = highest number of total claims paid for, if greater than 20

Independent Claims		Extra Claims	Fee ($)	Fee Paid ($)
	-3 or HP	=	x	=

HP = highest number of independent claims paid for, if greater than 3

Multiple Dependent Claims	
Fee ($)	Fee Paid ($)
x	=

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 C.F.R. 1.16(s).

Total Sheets		Extra Sheets		Number of each additional 50 or fraction thereof	Fee ($)	Fee Paid ($)
	-100	=	/50	= (round **up** to a whole number)	x	

4. OTHER FEE(S)

	Fee Paid ($)
Supplemental Information Disclosure Statement submitted after the first Office Action	$180.00

SUBMITTED BY

Signature	Thomas Q. Henry	Registration No. (Attorney/Agent)	28,309	Telephone	(317) 634-3456
Name (Print/Type)	Thomas Q. Henry			Date	May 17, 2007

CERTIFICATE OF MAILING OR TRANSMISSION

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Substitute for form 1449/PTO

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet	1	of	2

Complete if Known	
Application Number	10/551,840
Filing Date	January 20, 2006
First Named Inventor	SAMARITANI, Fabrizio et al.
Art Unit	1654
Examiner Name	Khanna, Hemant
Attorney Docket No.	7541-6

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (If known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
		US 4,496,537	01-29-1985	Kwan, Henry K.	
		US 4,589,402	05-20-1986	Hodgen, et al.	
		US 4,659,696	04-21-1987	Hirai, et al.	
		US 4,670,419	06-02-1987	Uda, et al.	
		US 4,746,508	05-24-1998	Carey, et al.	
		US 4,496,537	01-29-1985	Kwan, Henry K.	
		US 4,962,091	10-09-1990	Eppstein, et al.	
		US 5,087,615	02-11-1992	Chappel, et al.	
		US 5,128,453	07-07-1992	Arpaia, et al.	
		US 5,162,306	11-10-1992	Donaldson	
		US 5,270,057	12-14-1993	de Meere, et al.	
		US 5,356,876	10-18-1994	Espey, Lawrence L	
		US 5,374,620	12-20-1994	Clark, et al.	
		US 5,384,132	01-24-1995	De Meere, et al.	
		US 5,508,261	04-16-1996	Moyle, et al.	
		US 5,580,856	12-03-1996	Prestrelski, et al.	
		US 5,639,640	06-17-1997	Reddy, et al.	
		US 5,650,390	07-22-1997	Samaritani, et al.	
		US 5,661,125	08-26-1997	Strickland, Thomas Wayne	
		US 5,681,822	10-28-1997	Bornstein, et al.	
		US 5,733,572	03-31-1998	Unger, et al.	
		US 5,767,067	06-16-1998	Arpaia, et al.	
		US 5,811,096	09-22-1988	Aleman, et al.	
		US 5,889,110	03-30-1999	Hutchinson, et al.	
		US 5,929,028	07-27-1999	Skrabanja, et al.	
		US 5,945,187	08-31-1999	Buch-Rasmussen, et al.	
		US 6,066,620	05-23-2000	McGregor, et al.	
		US 6,136,784	10-24-2000	L'Italien, et al.	
		US 6,238,890	05-29-2001	Boime, et al.	
		US 6,267,958	07-31-2004	Andya, et al.	
		US 6,440,930	08-27-2002	Rinella, Jr., Vincent Joseph	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1]Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 2 of 2

Complete if Known	
Application Number	10/551,840
Filing Date	January 20, 2006
First Named Inventor	SAMARITANI, Fabrizio et al.
Art Unit	1654
Examiner Name	Khanna, Hemant
Attorney Docket No.	7541-6

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (If known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
		US 6,541,606	04-01-2003	Margolin, et al.	
		US 6,573,237	06-03-2003	Rinella, Jr., Vincent Joseph	
		US 2003/0072803	04-27-2003	Goldenberg, et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Application of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T[6]
		DE 41 17 078 A1	11-25-1882	Lohmann et al.		☐
		EP 0 318 081	05-31-1989	Jansen, et al.		☐
		EP 0 448 146	09-25-1991	De Ruiter, Marinus Arie		☐
		EP 0 603 159	06-22-1994	Pearlman, et al.		☐
		EP 0 652 766	07-29-1993	O'Connor, et al.		☐
		EP 0 668 073	04-14-1999	Igari, et al.		☐
		EP 0 736 303	08-25-1999	Gross, et al.		☐
		EP 0 853 945	07-22-1998	Skrabanja, et al.		☐
		EP 0 891 774	01-20-1999	Takada, et al.		☐
		EP 0 920 873	12-07-1998	Chang, et al.		☐
		EP 0 974 359	01-26-2000	Hoffmann, et al.		☐
		EP 1 191 099	06-30-1999	Itoh, et al.		☐
		CA 1,340,132	11-17-1998	Donaldson, Lloyd E.		☐
		FR 2782455	02-25-2000	Aleman, et al.		☐
		GB 1065127	04-12-1967	Serono 1st Farm		☐
		GB 839,300	08-25-1958	Organon Laboratories Limited		☐
		WO 92/21332	12-10-1992	Lohmann, et al.		☐
		WO 92/22568	12-23-1992	Moyle, et al.		☐
		WO 93/11788	06-24-1993	Samaritani, et al.		☐
		WO 94/03198	02-17-1994	O'Connor, et al.		☐
		WO 97/04801	02-13-1997	Andya, et al.		☐
		WO 97/17087	05-15-1997	De Young, et al.		☐
		WO 98/30592	07-16-1998	Hein, et al.		☐
		WO 99/21534	05-06-1999	Tallavajhala, et al.		☐

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SUPPLMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 7

Complete if Known	
Application Number	10/551,840
Filing Date	January 20, 2006
First Named Inventor	SAMARITANI, Fabrizio et al.
Art Unit	1654
Examiner Name	Khanna, Hemant
Attorney Docket No.	7541-6

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s) publisher, city and/or country where published	T[6]
		AKERS Michael J., "Considerations in selecting antimicrobial preservative agents for parenteral product development", Pharmaceutical Technology, May 1984, pp. 36-46.	☐
		AKERS, Michael J., "Excipient – Drug Interactions in Parenteral Formulations", Journal of Pharmaceutical Sciences, November 2002, Vol. 91, No. 11, pp. 2283-2300	☐
		AMIR, Syed M. et al., "Phenol, A Potent Stimulator of Adenylate Cyclase in Human Thyroid Membranes", Endocrine Research Communications, 8(2):83-95, 1981.	☐
		A.P.L.® Injection 5 000 IU and Injection 10 000 IU, http://home.intekom.com/pharm/akromed/apl-inj.html, December 12, 2002, pp. 1-2.	☐
		A.P.L.® (chorionic gonadotropin for injection, USP), For Intramuscular Injection Only, Physicians' Desk Reference, 51st Edition, p. 2805.	☐
		A.P.L.®, Physicians' Desk Reference, 12th Edition, page 625.	☐
		A.P.L.®, Physicians' Desk Reference, 19th Edition, page 537.	☐
		A.P.L.®, Physicians' Desk Reference, 34th Edition, page 592.	☐
		ARZNEIFORMENLEHRE, Paul Heinz List, Wissenschaftliche Verlagsgellschaft mbH, Stuttgart, 4th Edition, 1985, pp. 402-407.	☐
		Asellacrin®, Physicians' Desk Reference, 34th Edition, pp. 1605-1606.	☐
		Asellacrin®, Physicians' Desk Reference, 39th Edition, pp. 1940-1941.	☐
		BOIME, Irving et al., "Glycoprotein Hormone Structure-Function and Analog Design", Recent Progress in Hormone Research, Vol. 54, 1999, The Endocrine Society, pp. 271-289.	☐
		BONTEMPO, John A., "Chapter 5: Formulation Development", Development of Biopharmaceutical Parenteral Dosage Forms, pp. 109-142, published by Marcel Dekker, Inc.	☐
		COMBARNOUS, Yves, "Molecular Basis of the Specificity of Binding of Glycoprotein Hormones to Their Receptors", Endocrine Reviews, 1992. Vol. 13, No. 4, pp. 670-691.	☐
		CPMP Guidelines antimicrobial preservative inclusion, CPMP/CVMP/OWP/115/95, July 8, 1997, pp. 1-6.	☐
		de MEDEIROS, S.F. et al., "Stability of Immunoreative β-Core Fragment of hCG", Obstetrics & Gynecology, Vol. 77, No. 1, January 1991, pp. 53-59.	☐
		Epogen®, Physicians' Desk Reference, 51st Edition, pp. 489-494.	☐

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1]Applicant's unique citation designation number (optional). [2]Applicant is to place a check mark here if English language Translation is attache#449528

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U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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SUPPLMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet	2	of	7

Complete if Known	
Application Number	10/551,840
Filing Date	January 20, 2006
First Named Inventor	SAMARITANI, Fabrizio et al.
Art Unit	1654
Examiner Name	Khanna, Hemant
Attorney Docket No.	7541-6

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s) publisher, city and/or country where published	T[6]
		Fertinex™ (urofollitropin for injection, purified) for subcutaneous injection, Physicians' Desk Reference, 53rd Edition, pp. 2988-2989, published by Medical Economics Company, Inc.	☐
		Fertinex®, Physicians' Desk Reference, 55th Edition, pp. 3020-3022.	☐
		Follistim™ (follitropin beta for injection), Physicians' Desk Reference, 53rd Edition, pp. 2128-2132, published by Medical Economics Company, Inc.	☐
		Follistim®, Physicians' Desk Reference, 54th Edition, pp. 2092-2095.	☐
		Follutein®, Physicians' Desk Reference, 24th Edition, pp. 1249-1250.	☐
		FRANSSON, Jonas et al., "Solvent Effects on the Solubility and Physical Stability of Human Insulin-Like Growth Factor 1", Pharmaceutical Research 14(5):606-12, 1997.	☐
		FRENKEN, L.A.M. et al., "Analysis of the Efficacy of Measures to Reduce Pain After Subcutaneous Administration of Epoetin Alfa", Nephrology Dialysis Transplantation 9:1295-98, 1994.	☐
		FURUHASHI, M. et al. "Fusing the Carboxy-Terminal Peptide of the Chorionic Gonadotropin (CG) beta Subunit to the Common alpha-Subunit: Retention of O-linked Glycosylation and Enhanced in Vivo Bioactivity of Chimeric Human CG", Molecular Endocrinology, 1995, Vol. 9, No. 1, pages 54-63.	☐
		GARCIA-CAMPAYO, Vincenta et al., "Design of Stable Biologically Active Recombinant Lutropin Analogs", Nature Biotechnology 15:663-67, 1997.	☐
		GENNARO et al., "Parenteral Preparations", Chapter 84, Remington's Pharmaceutical Sciences (18th Edition, Mack Publishing. Co., 1990, see part 8 "Pharmaceutical Preparations and their Manufacture," pp. 1545-1569.	☐
		Glucagon, Physicians' Desk Reference, 19th Edition, pp. 703-704.	☐
		Glukor®, Physicians' Desk Reference, 19th Edition, page 844.	☐
		Gonal-F®, (follitropin alfa for injection), for subcutaneous injection, Physicians' Desk Reference, 53rd Edition, pp. 2991-2995, published by Medical Economics Company, Inc.	☐
		Gonal-F® (follitropin alfa for injection) For subcutaneous injection: Package Insert Code N1900101B, manufactured by Serono Laboratories, Inc., Randolph, MA, USA, published September, 1997.	☐
		Gonal-F®, Physicians' Desk Reference, 54th Edition, pp. 2942-2946.	☐
		HANSON, Musetta A. et al., "Introduction to Formulation of Protein Pharmaceuticals", Chapter. 7, pp. 209 – 233.	☐

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1]Applicant's unique citation designation number (optional). [2]Applicant is to place a check mark here if English language Translation is attached.

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(Use as many sheets as necessary)

Sheet	3	of	7

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Filing Date	January 20, 2006
First Named Inventor	SAMARITANI, Fabrizio et al.
Art Unit	1654
Examiner Name	Khanna, Hemant
Attorney Docket No.	7541-6

NON PATENT LITERATURE DOCUMENTS

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